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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/899,863	07/05/2001	Yoichi Fujii	NZK-128-1	4949

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EXAMINER	
WINKLER, ULRIKE	
ART UNIT	PAPER NUMBER
1648	8

DATE MAILED: 12/03/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/899,863	FUJII ET AL.	
	Examiner	Art Unit	
	Ulrike Winkler, Ph.D.	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *October 11, 2002* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-3 and 9-28* is/are pending in the application.

4a) Of the above claim(s) *9-28* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-3* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☒ Certified copies of the priority documents have been received in Application No. *09/333,521* .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *1* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Applicant's election with traverse of group I in Paper No. 7 is acknowledged. The traversal is on the grounds that the appropriate standard of restriction has not been met, and that invention of Group I-VI are so related as to be able to be examined together. The relatedness of the products does not deter from the fact that they are patentably distinct as pointed out by their different classification in the restriction requirement of paper No. 7. Therefore, restriction between groups I-VI is still deemed proper.

Applicant's urge that groups II and III use the protein of Group I and therefore should be searched together. A search of the protein database, required for the search of Group I will not reveal any antibodies (Group II) or chimeric antibodies (Group III) directed against the protein. The close relationship does not negate the fact that they are patentably distinct as pointed out by their different classifications in the restriction requirement of paper No. 7. Therefore, restriction between groups I-III is still deemed proper.

Applicant's urge that groups IV-VI use similar reagents and give similar results and therefore the methods should be examined together. The methods of group IV and V both are tools to diagnose AIDS, one uses the actual protein as the indicator for AIDS through antibody binding while the other method looks for DNA. The methods clearly differ in the material and techniques used although they diagnose the same disease. The similarity of the diagnosis does not negate the fact that the methods are patentably distinct as pointed out by their very different classifications in the restriction requirement of paper No. 7. Group VI is a method of screening for therapeutic agents, which comprises different method steps than those of Group IV and V. Therefore, restriction between groups IV-VI is still deemed proper.

Applicant's urge that that groups I, IV and VI are related methods because they rely on the protein of group I and therefore the search would be coextensive. The protein of group I can be used in materially different processes and therefore, restriction is deemed proper. The protein of group I can function as an antigen, a carrier protein or as a reagent for affinity purification. In addition, the restriction requirement of paper No. 7 indicates the groups are different based on their classifications and therefore restriction is deemed proper.

Based on the different classifications and the divergent literature search, the search will not be coextensive. The status in the art is such that it recognizes the difference in the groups.

Rejoinder of the process claims under MPEP 821.04 may occur if all rejoined claims meet the criteria of patentablilty including the requirements of 35 U.S.C. 101, 102, 103 and 112.

The requirement for the restriction/election is still deemed proper and is therefore made FINAL. Claims 9-28 are withdrawn from consideration. Claims 1-3 are examined and are rejected.

Priority

Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file of parent application 09/333,521. Note that the priority has not been perfected because a certified English translation has not been provided.

Information Disclosure Statement

An initialed and dated copy of Applicant's IDS form 1449, Paper No. 1, is attached to the instant Office Action.

The information disclosure statement filed July 5, 2002 fails to comply with 37 CFR 1.98(a)(3) because it does not include a concise explanation of the relevance, as it is presently understood by the individual designated in 37 CFR 1.56(c) most knowledgeable about the content of the information, of each publication listed that is not in the English language. It has been placed in the application file, but the information referred to therein has not been fully considered.

Note that all English references have been fully considered.

The reference by Fujii et al. (Saibo Kogaku 1997) has not been fully considered. The reference has been considered to the extent of the figures only, because it written in Japanese and no translation has been submitted.

The reference of Richard Bernarous (FR 2720068) has not been fully considered. The reference has been considered to the extent of the figures only, because it written in French and no translation has been submitted.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-3 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Instant claims are evaluated for enablement based on the Wands analysis. Many of the factors regarding undue experimentation have been summarized in *In re Wands*, 858 F.2d 731,8 USPQ2d 1400 (Fed.Circ.1988) as follows: (1) the nature of the invention, (2) the state of the prior art, (3) the predictability or lack thereof in the art, (4) the amount of direction or guidance present, (5) the presence or absence of working examples, (6) the quantity of experimentation necessary, (7) the relative skill of those in the art, and (8) the breadth of the claims. Such an analysis does not need to be specifically enumerate (points 1-8) but only needs to have a select few of the factors present discussed in a rejection.

The nature of the invention is a "functionally active homologue" of SEQ ID NO: 1. The specification does not provide a means by which one of ordinary skill in the art can ascertain what the applicant considers to be a "functionally active homologue" of the Nap protein. "Functionality" could be interpreted to mean: a.) an immunologically reactive fragment; b.) a fragment that is reactive with the monoclonal antibody disclosed in the specification; c.) a fragment that interacts with Nef; d.) a fragment that can interact with Nef or with an antibody or both. The limited definition of a "functionally active homologue" provided in the specification (page 10) is a protein binding to Nef. In addition the "functionally active homologue" may have deletions, insertion or substitutions of unlimited size, which is interpreted to include substitutions up to 285 a.a. in the 286 a.a. sequence of SEQ ID: 1. Without guidance of the biochemical characteristics required to be considered "functionally active" and given that the state of the art is not predicable, an ordinary artisan would not be able to make to make additions, deletions or substitutions to the protein with reasonable expectation of success. The applicant is inviting the

artisan to perform undue experimentation. The claims re rejected as not being enabled for a "functionally active homologue"

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-3 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The phrase "functionally active" renders the claims indefinite because the ordinary artisan would not know what is meant by this term. ". A "functionally active homologue" is defined in the specification as binding to Nef. In addition the "functionally active homologue" may have deletions, insertion or substitutions of unlimited size which is interpreted to include substitutions up to 285 a.a. in the 286 a.a. sequence of SEQ ID:1. Neither the claim nor the specification define the biochemical characteristics such as binding affinities, cellular location, and post-translational processes that have to be satisfied in order to be considered the a "functionally active homologue" of the protein.

The term "having/has " in claims 1-3 are a relative term which renders the claim indefinite. "Having" was noted by the court to be open language in Univ. of California v. Eli Lilly, 43 USPQ2d 1398 (CA FC 1997). The use of "having" in the claims opens the claims up to include unrecited elements even in large amounts consistent with the recitation of "comprising".

Therefore, the metes and bounds as to what is contemplated by the claims is not clear and the claims are rejected as being indefinite.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1 and 2 are rejected under 35 U.S.C. 102(b) as being anticipated by Liu et al (Journal of Biological Chemistry, 1997).

The instant invention is drawn to a protein present in CD4+ cells that is able to bind HIV Nef. The protein is approximately 35 kD in size, and identified as having an amino acid sequence represented by SEQ ID:1. A "functionally active homologue" is defined in the specification as binding to Nef, in addition the "functionally active homologue" may have deletions, insertion or substitutions of unlimited size. These deletion/substitutions and insertions are interpreted to include substitutions up to 285 a.a. in the 286 a.a. protein having a sequence represented by SEQ ID: 1.

Liu et al discloses a DNA encoding a 35 kD protein present in CD4+ cells that able to bind HIV Nef (see figure 4b). The methionine at position #1 in the amino acid sequence in the reference protein and the instantly claimed protein represented by SEQ ID NO:1 are identical. Therefore, given the unlimited number of mutations insertions and deletions, the instant invention is anticipated by Liu et al.

Conclusion

No claims are allowed.

SEQ ID: 1 is apparently free of the prior art and claims limited to SEQ ID NO: 1 would be allowable.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ulrike Winkler, Ph.D. whose telephone number is 703-308-8294. The examiner can normally be reached M-F, 8:30 am - 5 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel, can be reached at 703-308-4027.

The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4242 or for informal communications use 703-308-4426.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Ulrike Winkler, Ph.D. 12/2/02